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In the Supreme Court of the United States

October Term, 1986

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F. BAUER, JOHN D. BURROWS, RUSSELL C. HUMPHREY, JR., SIMON E. MILLER, IBA, INC., DANIEL BELSITO,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR WRIT OF CERTIORARI
To the United States Court of Appeals
For the Sixth Circuit

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QUESTIONS PRESENTED

The Sixth Circuit issued an opinion below which precludes defendants, charged with misbranding of an animal drug, from asserting the statutory defense of adequate directions for use specifically set forth in §502(f) of the Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. §352(f).

The decision further estops distributors of animal drugs used by dairy farmers from defending such actions because of administrative concessions by third parties in prior proceedings to which the distributors were not and could not be parties. The questions which arise are:

1. Can, consistent with due process, a trial court collaterally estop drug distributors from defending an FDA enforcement action because third parties made concessions in a prior administrative proceeding to which the distributors were not and could not be parties?

2. Did the trial and reviewing courts erroneously "defer" to agency interpretations of the FDCA which ignore both the plain language and Congressional intent of the statute by declaring that: (1) animal drugs' manufacturers' voluntary concessions restricting the resale of certain animal drugs establishes, as a matter of law, that the directions accompanying the drugs are inadequate for lay use; and (2) that "prescription or other order of a licensed veterinarian" cannot encompass an oral order from a veterinarian to an animal's owner?

LIST OF PARTIES AND RULE 28.1 STATEMENT

The Petitioners IBA, Inc., a Massachusetts corporation, and Daniel J. Belsito, President of IBA, are wholesalers of veterinary drugs who sell to independent distributors and dealers located across the United States. Neither IBA nor Belsito sell any veterinary drugs to end users, and, for purposes of the decision below, were "regularly and lawfully engaged in the distribution of drugs." App. at A43. Jerry Colahan is an IBA distributor in Ohio, and the other Petitioners are dealers and route salesmen who retail the drugs to dairy farmers and other farmers. The United States Attorney instituted this action on behalf of the Food & Drug Administration pursuant to 21 U.S.C. §332, which authorizes injunctive relief for violations of the FDCA.

IBA, Inc. has one subsidiary, Plymouth Manufacturing Company. It has no parent or other affiliated company.

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The Petitioners, Jerry J. Colahan, d/b/a IBA of Ohio, Norman F. Bauer, John D. Burrows, Russell C. Humphrey, Jr., Simon E. Miller, IBA, Inc., and Daniel Belsito, respectfully ask that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Sixth Circuit entered in this proceeding on February 5, 1987.

OPINIONS BELOW

The opinion of the Court of Appeals in *United States v. Colahan* is reported at 811 F.2d 287 and is reprinted in the Appendix ("App.") at A1. The opinion and order of

the District Court granting summary judgment is unprinted and appears at App. at A31. A prior Sixth Circuit opinion in this case was published at 635 F.2d 564 and is reprinted, App. at A49. The unpublished opinion of the District Court leading to the first appeal appears at App. at A58. This Court denied certiorari of the prior Sixth Circuit decision, 454 U.S. 831 (1981).

JURISDICTION

The decision of the Court of Appeals was entered on February 5, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1) and 28 U.S.C. §2101(C).

Jurisdiction was conferred on the Court of Appeals by the filing of a timely Notice of Appeal.

STATUTES AND REGULATIONS INVOLVED

The following statutes and regulations are reprinted in the Appendix:

1. Section 201 of the Food, Drug & Cosmetic Act, 21 U.S.C. §321(w) (App. A67).

2. Section 301 of the Food, Drug & Cosmetic Act, 21 U.S.C. §331(a-d) (App. A68).

3. Section 302 of the Food, Drug & Cosmetic Act, 21 U.S.C. §332(a-b) (App. A68).

4. Section 502(f) of the Food, Drug & Cosmetic Act, 21 U.S.C. §352(f) (App. A69).

5. Section 512 of the Food, Drug & Cosmetic Act, 21 U.S.C. §360b (App. A70).

6. 21 C.F.R. §201.105 (1986) (App. A77).

STATEMENT OF THE CASE

A. Background

Dairy farming is an industry which requires constant care to its primary resource, cattle. Such care includes administering veterinary drugs such as vitamin supplements, prophylactic medication, and salves and injections for irritations and illnesses. Many of these drugs are available in feed stores and supply stores and are routinely administered by the farmers.

Animal drugs, as human drugs, are under the general jurisdiction of the FDA to insure that: (1) drugs which are not both safe and effective are not marketed; and (2) adulterated or misbranded drugs are not sold.

In 1978, the FDA brought suit against Petitioners Jerry Colahan, and others, claiming that they received and sold various animal drugs that were misbranded under Section 502(f) of the FDCA, 21 U.S.C. §352(f)(1). Section 352(f)(1) deems a drug to be "misbranded," unless its labeling bears "adequate directions for use."[1]

That same section allows the agency to promulgate regulations exempting animal drugs from the "adequate directions" requirement where such directions are "not

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1. The statute provides:

A drug or device shall be deemed to be misbranded—

(f) Unless its labeling bears (1) adequate directions for use . . . *Provided*, that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

App. at A69.

necessary for the public health." Pursuant to this authority, the FDA promulgated 21 C.F.R. §201.105, exempting a veterinary drug:

> . . . which, because of toxicity or other potentiality for harmful effect, or the method of its use is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared . . . .

App. at A77. Those drugs are not misbranded if they bear a label reading:

> Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

App. at A77, and are in the possession of a person:

> . . . regularly and lawfully engaged in the . . . wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice.

Id.

The government made similar allegations in a suit filed in 1979 against Petitioners IBA, Inc. and Belsito in Massachusetts. IBA, Inc., however does not sell animal drugs retail. It sells only to independent dealers and distributors.[2]

The *IBA, Inc.* case was consolidated with the Ohio *Colahan* case.

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2. The Trial Court, for purposes of its decision, agreed that Petitioners were "regularly and lawfully engaged in the distribution of drugs." App. at A43.

B. FDA's Claims Against Petitioners.

Of the 17 animal drugs alleged to be misbranded, 15 were classified by the FDA as "new animal drugs" (NADs).[3] The FDA approved the interstate marketing of these drugs by accepting the NADAs submitted by the drugs' manufacturers. As part of the NADAs, the manufacturers stated they would place a restrictive label on the drugs:

> Caution: Federal law restricts this drug to sale by or on order of a licensed veterinarian.

In so doing, the manufacturers were able to receive approval whether or not the drugs were toxic or the directions accompanying the drug were adequate for lay (i.e. dairy farmers') use on cattle. The adequacy of the directions was not an administrative issue where the manufacturer agreed to use the "cautionary" labels.

If the Secretary approved the application within 180 days, neither notice nor a hearing was necessary and the NADA became effective without any opportunity for a party who would be affected by the restrictive labelling to participate. 21 U.S.C. §360b(c). App. at A72-73.

The government claims that 17 drugs sold by Petitioners were "misbranded."[4]

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3. A "new animal drug" is:

> . . . any drug intended for use for animals other than man . . . that . . . is not generally recognized, among experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .

21 U.S.C. §321(w), App. at A67.

4. Also at issue was whether IBA, Inc., which did not sell *any* veterinary drugs to end users, could be charged with misbranding on the sole grounds that it was the source of the drugs' overall marketing system. No evidence was offered to show that IBA, Inc. did or could "police" the resale of its veterinary drugs to farmers.

Two of the animal drugs were not subject to a pending NADA. The government claimed they were "misbranded," because they also had the cautionary label (though not required by any pending NADA) and were sold directly to farmers.

C. Procedural History.

The District Court issued an opinion in the *Colahan* case that, the FDA had no statutory authority to promulgate 21 C.F.R. §201.105, which allegedly establishes a "prescription" category for some animal drugs (App. at A58), enjoined the United States from further prosecution of the *IBA, Inc.* case on those grounds, and ordered transfer and consolidation of the *IBA, Inc.* case with the *Colahan* case. The Sixth Circuit reversed the Trial Court decision which invalidated §201.105 and remanded for further proceedings.

This Court denied certiorari. In their brief opposing certiorari, the United States acknowledged that the adequacy of the drugs' labels and directions was still to be litigated:

> [T]he Court of Appeals has neither permanently enjoined their distribution of the nine disputed drugs nor has it prevented petitioners from demonstrating that these drugs can be adequately labeled for lay use. In fact, the court directed the lower court to conduct further proceedings.

Brief in Opposition to the Petition, etc. (Case No. 80-2067) p. 13, n.11.

After remand from the Sixth Circuit, the consolidated cases were assigned to a magistrate for resolution of pretrial discovery disputes. The magistrate requested the

parties to brief four legal issues to narrow the scope of discovery. Instead the United States filed a Motion for Summary Judgment, now claiming that the presence of the "cautionary" label alone estopped Petitioners from proving that the drugs had adequate directions for lay use.

Petitioners opposed, filing a Brief and the Affidavit of Dr. William H. Lederer, a toxicologist who testified that he was in the process of analyzing each of the contested drugs and, so far, had concluded that the labeling of NAD dexamethasone was adequate for a lay person to use the drug in the treatment of animals. Prior to oral argument on the Motion for Summary Judgment, Petitioners learned that Dr. Lederer had died and filed a Motion for Leave to engage another expert.

The Motion for Leave was never ruled upon. The Court granted the government's Motion for Summary Judgment and entered an injunction which prohibited Petitioners from introducing 16 of the drugs into interstate commerce until they complied with 21 C.F.R. §201.105. In the absence of any evidence that Petitioners "misbranded" epinephrin, the Court sua sponte issued a declaratory order that sales of that drug in dosages exceeding 10 ml. would violate the misbranding statutes. In a post-judgment memorandum and order, the Court removed NAD nitrofurazone from the list of enjoined drugs "[u]pon stipulation by the government that this drug is presently permitted to be sold without a prescription . . . ." App. at A27-28. In other words, the government agreed that nitrofurazone was generally available OTC and thus not misbranded, even though it was classified as a new animal drug by the FDA and carried a cautionary label. The Court further clarified that in order to comply with 21 C.F.R. §201.105, there must be "direct communication . . .

oral or written . . . between a veterinarian and the dispenser of the drug." App. at A25. An oral order directly from the veterinarian to the animal's owner would not suffice. App. at A25. The Sixth Circuit affirmed.[5]

D. The Sixth Circuit Opinion.

The Sixth Circuit framed the issue as:

> . . . whether FDA can reasonably determine that approval of an NAD with labeling restricting resale of the drugs only upon a licensed veterinarian's order, renders that NAD subject to 21 C.F.R. §201.105 and the misbranding provisions without requiring FDA to demonstrate the toxicity of the drugs in a misbranding action.

811 F.2d at 292. The Court concluded that the FDA had no such duty "when the manufacturer itself proposes a label that states the NAD is not to be used except upon the order of a licensed veterinarian," and further:

> Defendants [Petitioners] should not be permitted to bypass FDA procedures and policies that seek to impose upon FDA the burden of proving a fact which was conceded in the original process by which FDA gave its approval to these NADs for the specific uses under defined conditions.

Id.

Although the Court referred to the "burden of proving a fact," burden of proof was not at issue. By affirming the summary judgment, the Circuit Court absolved the gov-

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5. Despite the Trial Court's holding that the order may be "oral or written," the Sixth Circuit held that the drugs could be sold only by "express prescription or other written order of a veterinarian." 811 F.2d at 293, App. at A12-13.

ernment from *any* showing regarding the toxicity or harmfulness of the drug, while Petitioners were denied the opportunity to prove the safety—i.e. nontoxicity—of the drugs.

As promulgated, 21 C.F.R. §201.105 applies, only where an animal drug is unsafe because of its "toxicity or other potentiality for harmful effect." The *Colahan* Court held that because these facts were "conceded" by the manufacturer, the government did not even have to show a prima facie case of toxicity, etc., and Petitioners were estopped from contesting the "conceded" facts.

The dissenting judge indicated that the issue to be considered should be:

> Whether the findings necessarily made during the NAD approval process, and which resulted in a requirement that these drugs bear the cautionary label, collaterally establish the factual predicate of section 201.105 that the drug is unsafe for use without veterinary supervision.

Id. at 295. He concluded that "all that can be presumed from the NAD application approval is that the drug is safe with the cautionary label; *it does not follow that the label is necessary to make the drug safe.*" *Id.* at 296 (Emphasis supplied). Therefore, in the dissenter's view, the District Court's:

> . . . ruling that the New Animal Drugs are covered by section 201.105 was based solely on the improper collateral use of the NAD application approval. *Thus, there was no showing that the drugs are in fact unsafe for use without veterinary supervision.* (Emphasis supplied.)

Id.

But further, the Court of Appeals completely ignored the question of whether animal drugs with adequate directions for lay use can *ever* be misbranded, regardless of the presence of a cautionary label. Section 352(f), the statutory authority for 21 C.F.R. §201.105[6] provides that animal drugs are misbranded *unless* they have adequate directions for use. The government conceded that the drugs at issue contained adequate directions for use or, at the very least that Petitioners could prove adequate directions for use on remand from the Sixth Circuit. Petitioners were prepared to show that the drugs had such directions; the District Court precluded them from doing so; and the Court of Appeals ignored this basic issue.

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6. The alleged statutory basis is, at best, tenuous. Whereas, Congress provided specific statutory authority for a prescription category of *human* drugs (§503(b), 21 U.S.C. §353), no such authority exists for animal drugs. The FDA must rely on the last sentence of 21 U.S.C. §352(f), which allows the FDA to promulgate regulations for animal drugs for which the misbranding prohibition "is not necessary for the protection of the public health."

REASONS FOR GRANTING THE WRIT

Under *Colahan*, any animal drug bearing the cautionary label is, as a matter of law, safe and effective only when distributed on the prescription or other order of a veterinarian. This is so even though the manufacturer may have volunteered to include the cautionary label to facilitate approval of the NADA. Further, by virtue of the presence of a cautionary label alone, adequate directions for lay use cannot be written for animal drugs distributed in the Sixth Circuit. This bootstrap argument contains no administrative factfinding at any point that the drug in question is potentially harmful if administered to cows by a dairy farmer or cannot contain adequate directions for lay use. Moreover, the Sixth Circuit rule binds parties who did not, and could not, participate in the FDA proceedings in which the NADA, with its labeling restrictions, was approved.

Finally, the Court gives undue deference to an overly narrow, irrational interpretation by the FDA of what is an order "of" a veterinarian.

I. THERE IS A CLEAR CONFLICT WITH PRINCIPLES OF COLLATERAL ESTOPPEL AND DUE PROCESS ENUNCIATED BY THIS COURT.

The Sixth Circuit held that Petitioners were estopped from challenging the necessity of the cautionary label by concessions made by the drugs' manufacturers in prior administrative proceedings. As this Court held in *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 329 (1971):

> Some litigants—those who never appeared in a prior action—may not be collaterally estopped without liti-

> gating the issue. They have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue which stand squarely against their position.

When, as in this case, the prior proceeding is administrative, due process requires not only that the party against whom it is sought to be applied participates, but that basic procedural guarantees are present:

> When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it *which the parties have had an adequate opportunity to litigate*, the Courts have not hesitated to apply *res judicata* to enforce repose.

United States v. Utah Construction & Mining Co., 384 U.S. 394, 422 (1966) (Emphasis added). *See also, Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 320 (1979) (in order to fulfill constitutional guarantees of due process and right to a jury trial, offensive use of collateral estoppel is limited to situations where the party against whom it is asserted had a full and fair opportunity to litigate the issue in a prior proceeding).

In *Ewing v. Mytinger & Casselberry*, 339 U.S. 594 (1950), this Court held that the FDA did not violate the due process clause of the Fifth Amendment when it exercised its discretion to determine that "probable cause" existed to institute mutliple seizures of defendant's allegedly misbranded drugs, so long as the defendant "has an opportunity to appear as a claimant and to have a full hearing before the court." 339 U.S. at 598.

In *CIBA Corp. v. Weinberger*, 412 U.S. 640 (1973), this Court held that when a *manufacturer* participated in, and received judicial review of, the FDA's determination

that its drug was a "new drug," it could not relitigate the issue:

> [P]etitioner, having an opportunity to litigate the "new drug" issue before FDA and to raise the issue on appeal to a court of appeals, may not relitigate the issue in another proceeding.

412 U.S. at 644. These cases compel the conclusion that defendants in an FDA enforcement proceeding must be given the right to challenge the FDA's characterization of the drug at issue unless the defendant can, and has, litigated the issue before the FDA with an opportunity for judicial review. At the very least, those characterizations cannot estop defendants where based on concessions by third parties without factfinding or judicial review.

In this case Petitioners never had the opportunity to contest or obtain judicial review of the FDA's conclusions that the challenged drugs were NADs that could be safely administered only under the supervision of a veterinarian. Under these circumstances, due process requires that Petitioners have the opportunity to prove that: (1) the challenged drugs are generally recognized as safe and effective and are therefore not NADs,[7] and (2) adequate directions for lay use can, and have been written, so that the cautionary label is unnecessary. Petitioners were summarily denied that right under the Sixth Circuit decision and this Court should accept certiorari to conform Sixth Circuit law to these long-standing federal principles.

Even assuming that Petitioners were properly precluded from asserting that the cautionary labels were un-

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7. For example, Petitioners should be permitted to demonstrate "bioequivalence" between the challenged drug and drugs presently available OTC, such as nitrofurazone.

necessary, the Sixth Circuit decision still obliterates the statutory intent of Congress that animal drugs shall be deemed to be misbranded only if they do not have adequate directions for lay use. The government has never alleged that the directions accompanying the 17 drugs were misleading, wrong, or inadequate for lay use. Their sole contention has been that although properly labeled, the drugs are misbranded by their method of sale. *See, e.g.*, 811 F.2d at 289, App. at A4.

The court below cited *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) as requiring deference to the FDA interpretation that the presence of a cautionary label foreclosed Petitioners' proof that the drugs had adequate directions for use. This Court recognizes, however, that:

> Judicial deference to an agency's interpretation of a statute "only sets the framework for judicial analysis; it does not displace it." . . . A reviewing court "must reject administrative constructions of [a] statute . . . that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement."

Security Industry Assn. v. Board of Governors, 468 U.S. 137, 143 (1984) (cites omitted).

Both legislative history[8] and FDA's prior interpretations[9] demonstrate that whether or not animal drugs

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8. *See, e.g.*, Kushen, *FDA: A Case Study in Administrative "Legislation,"* 24 THE BUSINESS LAWYER 261 (1968) (the legislative history of Durham-Humphrey Amendment "clearly supports" limiting prescription restrictions to drugs intended for use by man).

9. The FDA's own Compliance Policy Guide No. 7125.03, October 1, 1980, states:

> The definition of "prescription drug" in the FDC Act does not apply to drugs for animal use, but the requirement that

(Continued on following page)

carry a cautionary label, they cannot be misbranded if they have adequate directions for lay use. As noted above, the government has even admitted in prior pleadings before this Court in this case that Petitioners should be permitted to show the drugs have adequate directions for use. This Court should accept jurisdiction to perform the judicial analysis never performed below and confirm that defendants in a misbranding suit cannot be foreclosed from showing that the drugs at issue contain adequate directions for lay use.

Finally, assuming that sales of the animal drugs in question are properly restricted, and the drugs do not contain adequate directions for use, the courts below gave undue deference to the FDA's interpretation of its own regulation that an "other order of a licensed veterinarian" must be direct between the veterinarian and the dealer. The demonstrated legislative and administrative intent to permit owners to diagnose and treat their own animal's illnesses "as they see fit" (see fn. 9) mandates an interpretation which allows the owner to obtain the restricted drug after confirming that he or she had received an oral order from a veterinarian for the drug.

Footnote continued—

> the labelling of drugs bear adequate directions for use does apply to veterinary drugs. The interpreted view of Congress is that people have the right to treat their animals with any product for which reasonably adequate directions for safe use can be supplied in labeling.

See also, Bureau of Veterinary Medicine, HEW Pub. No. (FDA) 74-6012, Revd. May, 1978:

> The Congress specifically omitted animal drugs from prescription legend requirements on the basis that a man's animals are his private property and he may diagnose and treat their ailments as he sees fit. This means that in any case where adequate directions for lay use may be written, the animal drug must be freely marketed . . . .

This Court should accept judisdiction to enforce the "policy that Congress sought to implement."

II. THE DECISION IS IN CONFLICT WITH OTHER CIRCUITS.

The Sixth Circuit decision below conflicts with decisions of other circuits which recognize that defendants in misbranding actions can prevail by showing that the allegedly misbranded drugs have adequate directions for lay use or are generally recognized as safe and effective for their intended uses.

At least two circuits have interpreted *CIBA Corp., supra,* as a grant of concurrent jurisdiction between the FDA and district courts to determine the "new drug" status of a drug. Therefore, although the FDA may initially determine that a drug is a new drug, a defendant in a misbranding action brought by the FDA can challenge that status. Thus, in *United States v. Article of Drugs, . . . Lannett,* 585 F.2d 575 (3d Cir. 1978), the Third Circuit reversed summary judgment on a misbranding charge. The Trial Court held that the manufacturer was estopped from showing that the allegedly misbranded drug was not a new drug because it had not challenged the status before the FDA. Noting that the manufacturer had no prior opportunity to challenge the FDA determination and had no reason to write the FDA and request a change of classification until the misbranding action threatened its business, the Court of Appeals held: "The FDA and the District Court have given undue deference to the agency . . . ." 585 F.2d at 581.

The Court held that on remand Lannett could challenge the new drug status by showing that the challenged drugs were "bioequivalents" of drugs sold OTC. Petitioners

had offered to make a similar showing, but were held to be precluded from doing so. *See also, Premo Pharmaceutical Laboratories, Inc. v. United States,* 629 F.2d 795 (2d Cir. 1980) (the FDA and federal district courts have concurrent jurisdiction to determine new drug status in a declaratory judgment action). This Court approved *Premo* in *United States v. Generix Drug Corp.,* 460 U.S. 453 (1983) (certiorari accepted and Court of Appeals reversed where "the question is obviously important and because it has been decided differently in other Circuits," 460 U.S. at 456, citing *Premo* as the conflicting case).

Other courts have assumed that in a misbranding action the burden is on the government to show that drugs are misbranded because they do not have adequate directions for lay use. *United States v. Article of Device . . . Toftness,* 731 F.2d 1253 (7th Cir.), *cert. denied,* 469 U.S. 882 (1984) (where parties stipulated that where device was properly labeled as a prescriptive device, government met its burden of showing that it did not bear adequate directions for lay use); *United States v. X-Otag Plus Tablets,* 602 F.2d 1387 (10th Cir. 1979) (where parties agreed that if the challenged drugs did not meet the "new drug" status they were not misbranded, government sustained its burden of proving that the drugs did meet the "new drug" test).

The Sixth Circuit is, in fact, the only circuit which has stripped defendants of all defenses in injunction proceedings brought by the FDA. Interstate wholesalers, such as IBA, Inc., are therefore faced with conflicting standards in different areas of the country. This Court should grant certiorari to insure a uniform federal rule of animal drug distribution in the important agricultural industry of dairy farming.

III. THE DECISION BELOW WILL HAVE CONTINUING IMPACT ON ONGOING LITIGATION AGAINST THE ANIMAL DRUG INDUSTRY.

The United States' success in *Colahan* has led to the filing of similar suits. For example, in January of 1986, while the *Colahan* appeal was still pending in the Sixth Circuit, the Justice Department initiated an action against Southern Agriculture, Inc. of Tulsa, Oklahoma, and its president for misbranding veterinary drugs. Southern Agriculture, like some of the Petitioners, is a retail distributor of veterinary drugs with and without the cautionary labels and was accused of selling animal drugs bearing a cautionary label directly to farmers and ranchers.

If permitted to stand unchallenged, the *Colahan* decision will injure dairy farmers in the Sixth Circuit who depend upon comparably inexpensive, readily available animal drugs from wholesale and retail distributors and dealers. Farmers and ranchers, often isolated hundreds of miles from the nearest veterinarian, and responsible for hundreds of cattle, cannot practically or economically rely wholly on the services of veterinarians for the health of the animals. Under the rule of *Colahan,* a drug manufacturer's voluntary decision to avoid time and expense by offering to put a label on its drugs restricting its sale to the prescription or order of a veterinarian eliminates all flexibility and discretion for the farmer or the distributors of these drugs. A distributor haled into court for "misbranding" because drugs with the cautionary legend were sold directly to farmers are barred from proving that the animal drugs are generally recognized as safe and effective and/or are adequately labeled for lay use.

With the advent of *Colahan,* distributors in different parts of the country are subject to different legal standards.

Distributors and dealers in circuits that recognize a defendant's right to challenge the FDA's characterization of an animal drug as a "new animal drug" and/or the government's burden to show that directions are inadequate for lay use will be able to defend on those grounds. In marked contrast, distributors and dealers in the Sixth Circuit have lost that right. Ironically, in this case, the United States' own admission that one of the enjoined NADs was available OTC caused that drug to be removed from the injunction even though it had the cautionary label. A defendant in a misbranding action should not have to rely upon the largess of the government for its defenses, but should be permitted to a judicial determination based on evidence.

The United States has demonstrated its intention to sue distributors and dealers of veterinary drugs. This Court should insure that defendants in these actions have a full and fair judicial hearing.

CONCLUSION

Because the decision of the Sixth Circuit (1) is inconsistent with this Court's decisions on administrative collateral estoppel and due process, (2) gives undue deference to agency interpretations which conflict with the express language and legislative intent of the FDCA, and (3) conflicts with the rulings of other circuits, this Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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